K062438
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

Cindy Rumple
Cook OB/GYN
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-4891
August 18, 2004

OCT 27 2006

Device

Trade Name:	Bakri Postpartum Balloon
Common Name:	Postpartum Balloon
Proposed Classification Name:	Instrument, Manual, Specialized Obstetric-Gynecologic KNA

Predicate Devices:

The Bakri Postpartum Balloon is identical to the currently marketed SOS Bakri Tamponade Balloon Set (K013597). The purpose of this submission is to request clearance for the removal of uterine atony as a contraindication for use.

Indications for Use:

The Bakri Postpartum Balloon is intended to provide temporary control or reduction of postpartum uterine bleeding when conservative management is warranted.

Device Description:

The Bakri Postpartum Balloon is designed to provide temporary control or reduction of postpartum uterine bleeding when conservative management is warranted. The Bakri Postpartum Balloon is an inflatable tamponade balloon designed and proven to be affective in reducing and controlling postpartum bleeding. The construction of the Bakri Postpartum Balloon is silicone rubber. Biocompatibility testing has shown the materials to meet the test requirements. Bench testing has proven the products durability during simulated use. The Bakri Postpartum Balloon is provided sterile in peel open pouches and is intended for one time use. The testing, gathered data, and the history of the predicate device, the SOS Bakri Tamponade Balloon Catheter Set (K013597), which is identical in design and function proves that the Bakri Postpartum Balloon is a safe and effective device.

510(k) Premarket Notification
Bakri Postpartum Balloon
Cook Ob/Gyn

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program. The device will undergo packaging and sterilization procedures similar to devices currently marketed and distributed by Cook OB/GYN. Being similar with respect to indications for use, materials and physical construction to predicate devices, this device meets the requirements for section 510(k) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Cindy Rumple
Regulatory Affairs
Cook OB/GYN
1100 West Morgan Street
SPENCER IN 47460

OCT 27 2006

Re: K062438
Trade/Device Name: Bakri Postpartum Balloon
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: KNA
Dated: August 18, 2006
Received: August 21, 2006

Dear Ms. Rumple:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062438

Device Name: Bakri Postpartum Balloon

Indications for Use: The Bakri Postpartum Balloon is intended to provide temporary control or reduction of postpartum uterine bleeding when conservative management is warranted.

Prescription Use? __X____ (Part 21 CFR 801 Subpart D) ~~And~~/Or **Over-The Counter Use**_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRTIE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062438